Cost-effectiveness of a new combined immunosuppressive and anti-infectious regimen in kidney transplantation


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
This study assessed the clinical and economic impact of a new combined immunosuppressive regimen that included universal cytomegalovirus prophylaxis for patients undergoing kidney transplantation, in comparison with the standard immunosuppressive regimen. The new combined regimen was more effective, and slightly less expensive, than the standard approach from the perspective of the Swiss payer. The economic and clinical results were reported transparently and in detail, but the study methodology was characterised by some limitations on the clinical side of the analysis. Thus, caution will be required when interpreting the study results.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The objective of the study was to examine the clinical and economic impact of a new combined immunosuppressive regimen that included universal cytomegalovirus (CMV) prophylaxis for patients undergoing kidney transplantation, in comparison with the standard immunosuppressive regimen with prophylaxis only for CMV-positive donor/CMV-negative recipients.

Interventions
The standard immunosuppressive regimen consisted of basiliximab induction, cyclosporine, corticosteroids and mycophenolate mofetil or azathioprine. Antiviral prophylaxis with valacyclovir was administered only for CMV-positive donor/CMV-negative recipients. The new combined immunosuppressive regimen consisted of universal CMV prophylaxis with basiliximab induction, tacrolimus, corticosteroids and mycophenolate mofetil, with 450 mg daily valganciclovir prophylaxis for 3 months after transplantation in all patients at risk for CMV infection. Transplant patients with CMV-negative donor/CMV-negative recipient status received valacyclovir for 3 months.

Location/setting
Switzerland/hospital.

Methods
Analytical approach:
This economic evaluation was based on data from a single study. The time horizon was 1 year. The authors stated that the perspective of the payer was adopted in the study.

Effectiveness data:
The clinical data were derived from a retrospective observational study that covered the period January 2000 to July 2005. Of the 143 kidney transplant recipients identified at the authors’ institution in Lausanne over this period, 73 were treated with the standard regimen (between January 2000 and March 2003) and 70 were treated with the new combined regimen (between April 2003 and July 2005). After excluding ineligible patients (for which cost data were not fully available), 113 patients were finally included in the study sample. There were 53 patients in the standard group and 60 in the combined group. The baseline characteristics of the patient groups were comparable. The patients were followed up for 1 year post-transplantation. The key clinical outcome was the effect of treatment on the rate of acute rejection episodes and CMV infections.
Monetary benefit and utility valuations:
None.

Measure of benefit:
The health outcomes were left disaggregated. The key clinical end points were the rates of acute rejection episodes, CMV infections and recurrent CMV infections. Hospital stay, readmissions and outpatient visits with the two strategies were considered as secondary end points.

Cost data:
The health services included in the analysis were immunosuppressive and antiviral prophylaxis drugs, graft rejection treatment, CMV treatment, outpatient costs and hospital costs. A breakdown of the cost items was only partially given. Hospital-related resource use referred to the sample of patients enrolled in the clinical study and was estimated from the hospital information system. Outpatient consumption of resources came from individual patient charts. The hospital costs were extracted from the information system of the hospital, the outpatient costs were derived from Swiss official tariffs, and drug costs came from the Swiss Drug Compendium. The price year appears to have been 2006. The costs were in Swiss francs (CHF).

Analysis of uncertainty:
A deterministic sensitivity analysis was undertaken to consider potential differences in prices of health care resources in other countries. Thus, the costs of drugs and hospital services were varied by ± 50%.

Results
The rate of acute rejection episodes was 41.5% with the standard regimen and 6.7% with the new combined regimen, (p<0.001).

The rate of CMV infections was 47.2% versus 15.0%, (p<0.001).

The rate of recurrent CMV infections was 64.7% versus 12.5%, (p=0.030).

Readmissions were 68% versus 55%, (p=0.160).

Resource use was generally lower with the new combined regimen. The 1-year total costs per patient were CHF 39,957 in the standard group and CHF 36,204 in the new combined group, (p=0.112). This suggests that immunosuppressive and CMV drug costs were more than offset by savings associated with a reduction in complications.

When other medications not related to transplantation were also considered, the cost-difference was statistically significant in favour of the new combined regimen (CHF 44,164 versus CHF 39,174; p=0.044).

The sensitivity analysis confirmed the robustness of the base-case findings.

Authors' conclusions
The authors concluded that the new combined regimen including universal CMV prophylaxis in kidney transplantation was more effective than, and at least as expensive as, the standard approach from the perspective of the Swiss payer.

CRD commentary
Interventions:
The selection of the two strategies under examination was appropriate in that the proposed new approach was compared against the standard therapy for kidney transplantation. Specifically, the strategies reflected the change in patient management at the authors' institution. Clear descriptions of the two options were given.

Effectiveness/benefits:
The clinical data were obtained from a retrospective study, which is usually considered to be a weak source of evidence. Furthermore, the two therapies were administered over two different periods, which could have introduced some form of time-related bias; this was not taken into account in the analysis. Therefore, despite the baseline comparability of the
study groups, the impact of factors other than the study interventions (e.g. changes in medical practice) cannot be ruled out. In addition, the authors acknowledged that the evidence came from a relatively small sample of patients who were enrolled at a single institution, thus caution will be required if extrapolating these findings to other patient populations. These issues tend to limit the internal and external validity of the analysis. However, substantial differences in the clinical outcomes were found and these achieved statistical significance.

Costs:
Clear information on the analysis of the costs was given. The authors reported the costs as macro-categories, but other features of the analysis such as sources of costs and resource consumption, price year, and use of statistical tests for differences in costs and resources, were reported. Furthermore, the authors investigated variations in key items in order to consider different costs in other settings. Overall, the cost analysis was carried out transparently.

Analysis and results:
The costs and benefits were not combined because of the cost-consequences framework. The issue of uncertainty was addressed only in part to enhance the external validity of the analysis. As a result, only the cost estimates were varied in the sensitivity analysis. The authors noted some limitations of the analysis, such as the fact that some patients were excluded from the analysis because of incomplete records. Moreover, as the authors noted, the study was carried out at a single university hospital, which might not be representative of other medical institutions.

Concluding remarks:
Although this analysis was limited by the weak study design, the economic and clinical results were reported transparently and in detail. The authors' conclusions should be considered with a degree of caution.

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Bibliographic details

Other publications of related interest


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